SoftQuest Systems
assuring quality projects

June 30, 2024

Software in Medical Devices – Update for Q1/Q2 2024

The past year, as in previous years, life has not been easy for many reasons. According to an EY report, equity investment in medical device companies fell to its lowest point in seven years, declining 27% to $13.8 billion.

We have finally seen the FDA moving forward with new standards. The MDR/IVDR is still happening but is moving slowly. There is a major backup in getting to the notified body.

This is a continuation of the software updates I have been sending out. Please check out all the references to download and/or purchase. If you have any questions, please contact us.

Software is everywhere in medical devices and IVDs. The FDA and CE are becoming more pedantic in how they review and relate to software. The number of companies getting into the field is growing and the amount of software being developed for medical is exceptionally large.

There is an emphasis on "digital health" where the FDA is fast-tracking many devices (even though it is only software, it is still a medical device). Just because it is software only, doesn't mean that you are free from all the regulations. This includes a quality management system, risk analysis, etc.

Software Recalls Q1-Q2/2024

We have been following the recalls and there are a growing number of recalls listed where software played a role in the recall. It is interesting to note that software is the leading cause of recalls in the FDA for the past 10 years. This trend does not look like it will change.

The following are additional examples of recalls involving software directly as listed on the FDA website, including Israeli developed software. There may be more but classified not under software. There are a large number of class I recalls after patients were severely injured and even died. The descriptions given for the recall are taken from the FDA database. For further details on the recalls, you can check them out on the FDA's recall database.

Please note that the content for each recall is taken from the FDA database and is not our content.

Hashomrim 61, Rehovot 7622607, Israel
Tel: 972-50-5357221
Web: www.softquest.co.il
E-mail: mikez@softquest.co.il

1) **Philips Respironics, BiPAP V30 Auto Ventilator, Class I** – Potential for devices to experience interruption/loss of therapy during a Ventilator Inoperative alarm. This may lead to hypoventilation, mild to severe hypoxemia, hypercarbia, respiratory failure/insufficiency, or potentially death in the most vulnerable patients.
2) **OptumHealth Care Solutions, Optum Nimbus II Plus, Class I** – Nimbus II Plus, Infusion Pump Systems, manufactured by InfuTronix, are being removed the from the market due to multiple potential failure modes, including battery failure, upstream occlusion, system errors, drug product leakage, high or low flow rate, or damaged pump housing.
3) **SonarMed, AW-M0001 SONARMED MONITOR, Class I** – Software anomaly resulted in failure to detect a partial obstruction in 2.5 mm sensors and up to 3mm distal to the sensor.
4) **Philips Respironics, Trilogy Evo O2, Class I** – Potential for sudden loss of ventilation due to Battery Depleted or Loss of Power alarm while unit has sufficient power.
5) **InfuTronix, Nimbus Administration Set, Class I** – InfuTronix is removing the Nimbus Infusion Pump Systems from the market due to multiple potential failure modes, including battery failure, upstream occlusion, system errors, drug product leakage, high or low flow rate, or damaged pump housing.
6) **Baxter Healthcare Corporation, Exactamix Pro 1200, Class I** – An error was identified in software versions 2.0.8 and 2.1.8 while using the "Use Some Overfill" feature which may lead to over-delivery of an ingredient. This issue can result in redundant ingredient delivery of the requested overfill volume.
7) **Tandem Diabetes Care, t:connect mobile app, Class I** – During normal use, the mobile app version 2.7 may crash and be automatically relaunched by the iOS operating system. This cycle intermittently repeats, which leads to excessive Bluetooth communication that may result in pump battery drain and may lead to the pump shutting down sooner than typically expected. Pump shutdown will cause insulin delivery to suspend, which could lead to an under-delivery of insulin and may result in hyperglycemia, including severe hyperglycemia.
8) **Fresenius Kabi, LVP Software of the Ivenix Infusion System (IIS), Class I** – Software has anomalies that have the potential to cause underdose, overdose, or delay in therapy which could lead to serious patient harm or death.
9) **Smiths Medical ASD, Medfusion Model 3500 Syringe pump, Class I** – Medfusion syringe pumps, with software versions before v6.0.0, may have the following issues:1. Delivery During Motor Not Running High Priority Alarm, 2. Infusion Restarted with Incorrect Parameters, 3. Screen Lock, 4.

Interruption of Bolus or Loading Dose Delivery, 5. Pump Displays Incorrect Bolus/Loading Dose, 6. Loading/Bolus Dose Below the Minimum Recommended Rate, 7. Motor Rate Error, 8. Incorrect Recall Last Settings, 9. Corrupt Configuration, 10. Auto Lock, 11. Toolbox Configuration Loading Dose Time Values. Smiths Medical corrected all issues included in this notification in previous software updates and the corrections were carried forward into all subsequent software releases. Please ensure you have the most recent Medfusion software (v6.0.0) installed on your pumps.

10) **Medtronic Navigation, Stealth S8 Clinical Software Application, Class I** – Due to a software issue, there is the potential for a missing digit, letter, or decimal in either the "distance to target" or "tip stop point" display during navigation.
11) **Thoratec, HeartMate Touch Communication System, Class I** – Due to software and controller systems that results in unexpected pump start or pump stop.
12) **Insulet, Omnipod 5 App, Class I** – The bolus calculator is not recording the decimal point if it is the first value entered when changing a bolus dose. This may lead to an over-delivery of insulin to the user if the user does not recognize the error on the bolus calculator screen or the confirmation screen prior to starting the bolus.
13) **Canon Medical System, Vantage Titan, Class II** – For some MRI systems, it has been found that some of the maximum Spatial Field Gradient (SFG) values displayed in "System Information" of the operation window and some of the maximum SFG values described in the safety manual are lower than the correct values, which may cause a patient with an MR conditional device to feel some discomfort during the MR scan.
14) **Stryker Orthopaedics, Total Knee Arthroplasty, Class II** – Application software intended to be deployed on Mako 3.0, part number 209999, and Mako 3.1, part number 219999, observed an increase in the Software Error #3 (SE3) error code when a Mako System shutdown or a Mako System restart is not performed prior to switching between applications (i.e. TKA to THA), resulting in delay in treatment.
15) **Boston Scientific Neuromodulation Corporation, Vercise Genus Deep Brain Stimulation (DBS) Implantable Pulse Generator IPG, Class II** – Deep Brain Stimulation (DBS) Implantable Pulse Generator (IPG) may experience routine system check during IPG charging, which may cause device reset. The device reset could lead transient loss of stimulation; patients may experience undesired sensations, transient worsening of movement disorder symptoms, which may lead patient to request surgical intervention for replacement or revision.
16) **Channel Medsystems, Cerene Cryotherapy Device, Class II** – Error code 003 was not listed in certain rows of the Device Instructions for Use

Troubleshooting section (i.e., Table 22. Summary of LCD Messages and Error Codes).

17) **Fresenius Medical Care Holdings, Novalung Console, Class II** – Issue related to Novalung sensor box, which is a component of the Novalung Console (Part Number F30000163). In certain instances, error messages #206 (yellow) and #208 (red) technical failure, flow measurement during use of the Novalung system.
18) **NRT X-RAY, Intelli-C, Class II** – X-ray system C-arm may experience uncontrolled motion if 1) AC motor controller firmware has a faulty setting, 2) the Motor/gear assembly is worn, 3) CAT movement is driven at maximum speed and angulated more than 75 deg. from vertical, and 4) the emergency stop or touch guard is activated during the breaking sequence, which could lead to the C-arm hitting the patient or operator.
19) **Ion Beam Applications, BA Proton Therapy System, Class II** – There is a risk of mistreatment as irradiation is not prevented when some safety parameters are out of tolerance.
20) **Siemens Healthcare Diagnostics, Atellica CH Iron3 - IVD, Class II** – Potential for falsely elevated Chol_2, LDLC, and Trig_2 results on the Atellica CH and Atellica CI analyzers when the previous result in the cuvette was Iron3. Results in a positive bias ranging from 2-16% -impacts calibrator, quality control (QC), and patient results.
21) **Blue Belt Technologies, CORI REAL INTELLIGENCE Robotic Drill, Class II** – Possibility that the user is unable to resolve drill disconnection error messages.
22) **Philips North America, BrightView, Class II** – While using Pre-Programmed Motion during an extrinsic quality assurance scan, a gap is created between the patient support and the detector, which may present a potential extremity entrapment hazard. Risk to patients may include fracture, body part loss of function/debilitation, muscle or ligament sprain or strain, laceration, crush injury, abrasion, or contusion.
23) **Ortho-Clinical Diagnostics, VITROS 5600 Integrated System, Class II** – A software defect affecting VITROS Systems running VITROS Software Versions 3.8.1 causes QC baseline statistics to not update as expected when changed by the user. This may cause erroneous patient results to be reported.
24) **Stryker Leibinger, ENT Software with TGS, Class II** – Unreleased software was installed on customer systems resulting in the visual feedback on the screen to show the points to be off from the physical reference point of the pointer or suction.
25) **Covidien, Valleylab FT10, Class II** – On November 16 and 20, 2023, Covidien LLC (Medtronic Company) issued an "Urgent: Medical Device Correction". Immediately notify all personnel in all care environments in which the Valleylab" FT10 Energy Platform. 2. Update ValleylabTM FT10 Energy

Platform to software version 4.0.4. For additional information see customer communication letter 3. Until the software is updated, the Valleylab "FT10 Energy Platform and LigaSure" devices can continue to be used as instructed in the User Guide and per your facility protocols. 4. Complete the attached Customer Confirmation Form and return it as directed to confirm your receipt and understanding of this information.

26) **Tornier, Stryker Blueprint Software, Class II** – The software bug allows for case planning with anatomic glenoid Perform / Perform Augmented implants and anatomic humeral Tornier Flex implant configurations that are incompatible and do not have regulatory approval.
27) **Reflexion Medical, RefleXion X1 Radiotherapy System, Class II** – A potential dose error exists for patients treated with an out of session SCINTIX partial fraction.
28) **Philips North America, Patient Information Center iX and Patient Information Center iX Expand, Class II** – Event Catalog information does not save when copied and transferred from one unit to another.
29) **Ossur, RHEO KNEE XC, Class II** – Due to firmware issues with the prosthetic knee, there is the potential for unintended warnings and device shutdown which could result in patient falls.
30) **Raysearch Laboratories, RayStation, Class II** – Potential for reported SSD to be too high.
31) **Siemens Medical Solutions, ACUSON Maple Diagnostic Ultrasound System, Class II** – On ultrasound systems, when Cardiac DICOM SR feature is configured to display either minimum or maximum measured value, and multiple cardiac region measurements are made, and results are exported into the SR feature, then The SR viewer will display the LAST measured value, not min or max, which could contribute to patient condition misdiagnosis or negatively influence patient management decisions.
32) **Philips North America, Incisive Computed tomography X-ray system, Class II** – Patient tabletop moved out to the home position during scan initialization, may cause operator/bystander staying by the rear of the table to collide with the moved tabletop and be injured.
33) **Life Technologies Corporation, Torrent Suite Dx Software, Class II** – Torrent Suite Dx Software versions 5.14 and earlier used in connection with Ion PGM DX Systems exploitation of the vulnerability by a threat actor may allow them to alter settings, configurations, software, or data on the instrument.
34) **Fresenius Kabi USA, LVP software of the Ivenix Infusion System (IIS), Class II** – Retroactively reported corrections from 2023: 1) A software defect may cause an incorrect (Fail-Stop) alarm when an administration set is loaded or coupled while the pump is executing the power-up sequence. May lead to delay in therapy. 2) Alert is not annunciated informing the clinician that the bolus cannot be delivered when the entered bolus dose exceeds the Care

Profile Hard Rate Max limit and Rapid Bolus is selected. May lead to over infusion. Both issues were resolved in all fielded product in software version 5.8.0, which was installed in affected units May thru August 2023.

35) **FUJIFILM Healthcare Americas, Synapse PACS, Class II** – Measurements on a Secondary Capture 2D image, that does not have pixel spacing in the DICOM header, when combined with a Breast Tomo Series results in incorrect measurements.
36) **Zyno Medicalv, Z800 Large Volume Infusion Pumps, Class II** – When utilizing the patient query feature on the Zyno Medical Z-800WF pumps with software version 5.2.05, the alarm volume may inadvertently revert from a higher volume setting to a low one, causing potential delays in therapy and in extreme cases, associated risk of organ failure or death.
37) **PTW-FREIBURG, Software VERIQA, Class II** – If the user excludes voxels from the Gamma calculation that are below a dose threshold (Suppress gamma calculation), the Gamma Passing Rate (GPR) calculated for individual ROIs is not correct. The GPR calculated by VERIQA overestimates the correct GPR. The evaluation can therefore show false positive results.
38) **IMPULSE DYNAMICS, OPTIMIZER model CCM X11 implantable pulse generator (IPG) devices - Smart Mini and Lite, Class II** – OPTIMIZER devices may cease to deliver CCM therapy if the device incorrectly detects a charging error. This may cause patients to experience heart failure symptoms similar to before implantation of the device.
39) **Abiomed, Automated Impella Controller, Class II** – Retrospective reporting for the release of Technical Bulletin IMP-2643 AIC Version 8.5 Software Update Available. The update resolved an issue in version 8.4 where a pump was not recognized by the AIC.
40) **FUJIFILM Healthcare Americas, Synapse CV 6 with AR, Class II** – The LV Mass (2D Bullet) equation may be calculated incorrectly, resulting in a variance in the mass of the left ventricle (LV Mass). If used as a main factor for diagnosis, there is a risk of misdiagnosis or incorrect treatment plan of a patient, resulting in long-term health consequences or serious deterioration of health.
41) **PHILIPS MEDICAL SYSTEMS, CombiDiagnost, Class II** – While performing a fluoroscopy examination, there is a potential that the Radio Fluoroscopy (RF) viewer will also display a previous patient's radiography images. If the issue occurs, there will be differences in image content, image format and image size.
42) **Getinge USA, Flow-c Anesthesia System, Class II** – An Urgent Medical Device Correction notice dated December 21, 2023 was issued via FedEx. The letter advises customers to examine inventory immediately to determine if you have any affected product. Directions are outlined for 1) Users with system version 4.8 and above with a Flow Anesthesia System connected to

Connected Services directly via the Ethernet port on the Flow Anesthesia System (i.e., without a Getinge Connect module) and for 2) Users with system version 4.7 and below with Flow Anesthesia System connected to Remote Services via ethernet cable.

43) **Beckman Coulter, DxI 9000 Access Immunoassay Analyzer, Class II** – There are potential performance issues found in the DxI 9000 Access Immunoassay Analyzer, including: 1) Access Ultrasensitive Insulin users who configure SI units (pmol/L) applies an incorrect conversion factor; 2) System provides numerical results that are below the lowest reportable result if laboratory chooses to report assay results in units of measurement other than the defined default units; 3) A result of 0 incorrectly reported when the system utilizes an expression that utilizes non-numerical symbols (e.g., > or <) to derive a calculated test as part of result reporting; 4) Reserve volume is enabled and the assay LIS code is not the same as the assay Test ID. These issues could potentially lead to erroneous results or delay reporting results for multiple analytes.
44) **Xcision Medical Systems, GammaPod - Treatment Planning System, Class II** – Wrong structures imported into the GammaPod Treatment Planning System allowed an RTSS generated from a previous CT scan to be selected.
45) **Abbott Diabetes Care, FreeStyle Libre 3 App, Class II** – If using affected glucose monitoring app on Android 13 Operating System, extended periods of signal loss may be experienced, due to app not connected, which could impact ability to receive glucose reading/alarms, which could lead to undetected low or high glucose, which could result in delayed treatment: not taking insulin (for high glucose), or not taking glucose (for low glucose) when required.
46) **Philips North America, Patient Information Center iX, Class II** – Push notifications may fail to send to the user under certain conditions. This could potentially result in patient harm due to delay in detection of a change in patient condition.
47) **Baxter Healthcare, XScribe Cardiac Stress Testing System, Class II** – Potential distortion identified in electrocardiogram (ECG) readings when the Source Consistency Filter (SCF) is enabled.
48) **Siemens Medical Solutions, Sensis Vibe Hemo, Class II** – The possibility of the Sensis documentation functionality application to crash.
49) **WOM World Of Medicine, Aquilex Fluid Control System, Class II** – The display of inflow volume can reach its limit of 30,000 ml during long procedure and the inflow volume display will freeze at the maximum value while the deficit will start counting backwards until 0 ml is reached and may result in fluid overload.

50) **CareFusion, BD Alaris System Manager, Class II** – Due to a software issue there is the potential that the PC unit may not connect to the server. This could impact wireless data transmission to and from the server.

EU AI Act

On 13 March 2024, the AI Act was approved by the EU parliament for adoption. The final text of the law will apply from 2 August 2026 with some exceptions.

One crucial distinction in the AI Act is between a "provider" and a "deployer" of AI. While most rules in the AI Act target the deployer, some target the provider. This includes cases where a third party's infrastructure is used for providing the service.

- A provider is a natural or legal person, public authority, institution, or other body that develops an AI system (or a GPAI model) or has it developed in order to place it on the market, put it into circulation, or put it into operation under its own name or brand—whether for payment or free of charge—like a manufacturer in the sense of product law.
- A deployer of the AI system (still misleadingly referred to as a "user" in some EU documents) is a natural or legal person, public authority, institution, or other body that uses an AI system under its own responsibility, unless the AI system is used in the context of a purely personal and non-professional activity.

https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence

Tandem Diabetes Care's recall

On 8 May 2024, Tandem Diabetes Care's recall of Version 2.7 of the Apple iOS t:connect mobile app used with its t:slim X2 insulin pump with Control-IQ technology has been labeled Class I by the U.S. Food and Drug Administration (FDA).

The company is recalling version 2.7, which was released February 12 on the iOS platform, of the app for the t:slim X2 pump by a correction, not product removal. The company identified a software issue that can cause the mobile app to crash and be automatically relaunched by iOS.

The cycle repeats intermittently, leading to excessive Bluetooth communication that can cause pump battery drain and causing it to shut down sooner than expected. This will suspend insulin delivery which can result in high blood sugar or even diabetic ketoacidosis, Tandem warned.

The company has received reports of 224 injuries as of April 15, with no reports of death.

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

The Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program was issued on March 15, 2024. This draft guidance document is being distributed for comment purposes only.

https://www.fda.gov/media/177009/download

Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act

This draft guidance document was issued on March 13, 2024. It was distributed for comment purposes only. When this guidance is finalized, it will supersede "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," issued September 27, 2023.

https://www.fda.gov/media/176944/download

Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together

In March 2024, the FDA issued the **Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together** paper. This is published jointly by CDRH, CBER, CDER and OCP.

https://www.fda.gov/media/177030/download?attachment

Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products

This draft guidance document was issued on 5 July 2024. The purpose of this guidance is to support *use-related risk analysis* (URRA) and how a URRA, along with other information, can be used to determine human factors (HF) data needs during product development and to support a marketing application.

https://www.fda.gov/media/179858/download

MDCG 2020-16 rev 3 - Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746

The Medical Device Coordination Group (MDCG) issued in July 2024 the update for this guidance. This guidance provides classification rules for IVDDs.

https://health.ec.europa.eu/document/download/12f9756a-1e0d-4aed-9783-d948553f1705_en?filename=md_mdcg_2020_guidance_classification_ivd-md_en.pdf

FDA Recognized Consensus Standards

The following are some of the consensus standards recognized by the FDA in this first half of 2024:

- ISO/IEEE 11073-10408 Second edition 2022-12: Health informatics - Point-of-care medical device communication - Part 10408: Device specialization - Thermometer
- ISO/IEEE 11073-10415 Second edition 2022-12: Health informatics - Point-of-care medical device communication - Part 10408: Device specialization – Weighing Scale
- ISO/IEEE 11073-10404 Second edition 2022-12: Health informatics - Point-of-care medical device communication - Part 10408: Device specialization - Pulse oximeter
- ISO/IEEE 11073-10407 Second edition 2022-12: Health informatics - Point-of-care medical device communication - Part 10408: Device specialization - Blood pressure monitor

- ISO/IEEE 11073- 20601 Third Edition 2022-12: Health informatics - Point-of-care medical device communication - Part 20601: Application profile - Optimized exchange protocol
- IEEE Std 11073-10101b-2023: Health informatics - Point-of-care medical device communication. Part 10101: Nomenclature
- IEEE Std 11073-10700-2022: Health Informatics - Device Interoperability Part 10700: Point-of-Care Medical Device Communication - Standard for Base Requirements for Participants in a Service-Oriented Device Connectivity (SDC) System
- IEEE Std 11073-10206-2022: Health informatics - Device interoperability - Part 10206: Personal health device communication - Abstract Content Information Model

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions - Update

The guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" was released 27 September 2023, and we have received feedback from the FDA on submissions made.

Examples of the deficiencies include the following:

1) Provide a threat modeling using a threat modeling methodology
2) Provide a cybersecurity risk assessment (i.e., CVSS, IEEE 11073-40101-2020, NIST SP 800-30)
3) How the device detects, monitors, logs, and/or alerts users of security compromise
4) Provide a reasonable assurance that the device and related systems are cybersecure
5) Describe the end-to-end process for delivering updates to the device
6) Describe the end-to-end process for deploying updates from the cloud environment including any risks identified and mitigations implemented
7) Provide a SBOM
8) Provide security testing, including, but may not be limited to, requirement verification testing, static and dynamic code analysis, malformed input (fuzz) testing, vulnerability scanning, and penetration testing
9) Provide a plan to monitor, identify, and address, as appropriate, in a reasonable time, post market cybersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and related procedures
10) Provide cybersecurity labeling for the user

https://www.fda.gov/media/119933/download

Content of Premarket Submissions for Device Software Functions

Since the FDA has released the **Content of Premarket Submissions for Device Software Functions** guidance a year ago, there have been a number of submissions we have been in volved with under this new guidance. This guidance covers:

- firmware and other means for software-based control of medical devices
- stand-alone software applications
- software intended to be operated on general-purpose computing platforms
- dedicated hardware/software medical devices
- accessories to medical devices when those accessories contain or are composed of software

The guidance applies to the following submissions of software (either as part of a device or as the device):

- Premarket Notification (510(k))
- De Novo Classification Request
- Premarket Approval Application (PMA)
- Investigational Device Exemption (IDE)
- Humanitarian Device Exemption (HDE)
- Biologics License Application (BLA)

The level of documentation is based on the device's intended use and does away with the Level of Concern (LOC). There are two levels of documentation:

1) Basic Documentation
2) Enhanced Documentation

According to the guidance, Enhanced Documentation should be provided for any premarket submission that includes device software functions, where any of the following factors apply:

1) The device is a constituent part of a combination product.
2) The device (a) is intended to test blood donations for transfusion-transmitted infections; or (b) is used to determine donor and recipient compatibility or (c) is a Blood Establishment Computer Software.
3) The device is classified as class III.
4) A failure or latent flaw of the device software function(s) could present a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use. These risk(s) should be assessed prior to implementation of risk control measures.

If the device does not meet the criteria for Enhanced Documentation, then it should be submitted as Basic Documentation.

https://www.fda.gov/media/153781/download?attachment

How Frequently Can you Release Medical Device Software?

We have been asked numerous times by our clients: "How frequently can we release our medical-device software?" Usually, the person asking is a software-engineer who has used agile in another field and is used to frequent rapid releases.

The short answer is: You can release software updates as frequently as you want so as long as:

1) The changes don't require regulatory submissions
2) You can produce all of the necessary design change documentation.

In practice, we've seen software development firms who can release updates as quickly as every two weeks. Usually, however, monthly or quarterly releases are more realistic.

If you need more information on this, please contact us.

IEC 62304 Update

There is work in reconvening the committee but this is a slow process. We'll keep you informed if anything happens.

Tools to Investigate

We are recommending the use of various tools in order to make the FDA/CE happy and, at the same time, improve the quality of the software. These tools include (but definitely not limited to):

- Defect management
- Code control
- Static code analysis

- Dynamic code analysis
- Unit and integration testing
- Continuous integration
- Penetration testing
- Functional safety
- SBOM

When choosing the tools, check the local support. Even though everyone offers Internet support, nothing beats having the support done locally by someone who has the experience and speaks your language. For further information concerning the tools, please feel free to contact us and we'll refer you to the tool vendors with the tools you need.

Various tools to think about (they cost a little money but will save much more):

1) Static Code Analysis - Parasoft, Coverity, Polyspace, SonarQube, Axivion, PQRA, Klocwork, Grammatech, LDRA, IAR C-STAT
2) SBOM – Merge Base, FOSSA, Sonatype, Insignary, Snyk
3) Defect management – Jira, Asana, Azure DevOps
4) Unit & integration testing – Cantata
5) Safe embedded operating systems – Seggar RTOS

If you need more information on the tools and where to purchase them (with support), please contact us.

Summary

There are many ways to screw up your software in the medical device whether it is embedded in dedicated hardware (also known as SiMD – Software in a Medical Device) or stand-alone health software (also known as SaMD – Software as a Medical Device). It doesn't take too much talent to do this (as we all know) and companies are doing it daily. Many companies mess up royally and don't know how to get out of the mess. In many cases, they don't even know that they are in deep trouble until the recall is issued.

You can work properly without breaking the bank. There are many ways to handle the software development/maintenance life cycle and the software validation.

If there are any questions or requests, please feel free to contact us.

Mike

Hashomrim 61, Rehovot 7622607, Israel
Tel: 972-50-5357221
Web: www.softquest.co.il
E-mail: mikez@softquest.co.il